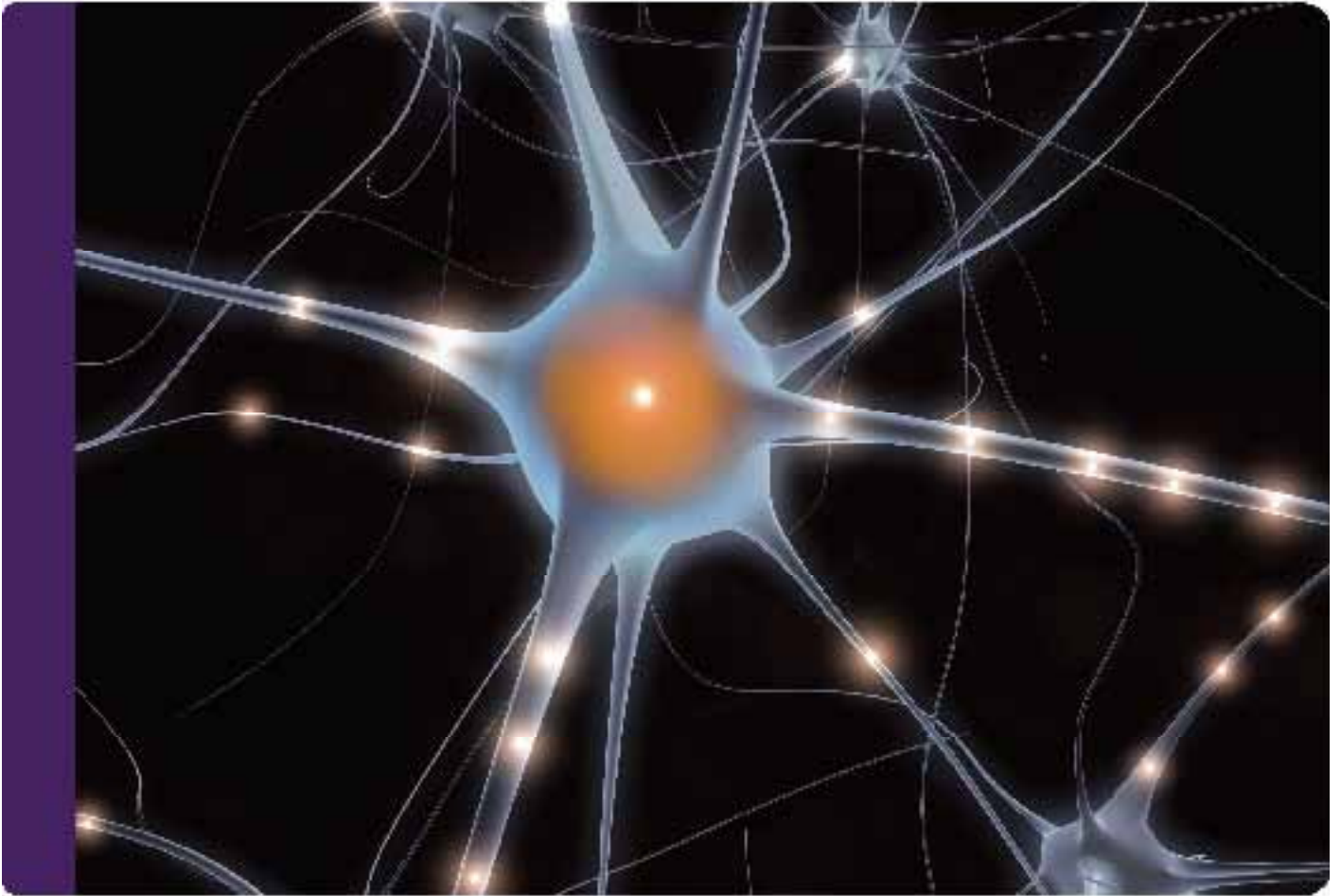




Field Fisher Waterhouse



Life Sciences & Healthcare



“The leading firm for healthcare regulatory work.”

Chambers UK, 2006 - Healthcare

About us

Field Fisher Waterhouse LLP is a full service European law firm with offices in Brussels, Hamburg, London and Paris. In addition to our European offices, we have exclusive relationships with Spanish firm Jiménez de Parga and Italian firm La Scala. We also have strong affiliations with firms in the Czech Republic, Hungary and Poland.

Our reach means we attract a broad range of clients throughout Europe, Asia and the US. We advise our international clients on domestic and EU law and have extensive experience advising on multi-jurisdictional matters.

With more than 120 partners and over 220 other lawyers, we assist a wide range of international clients, advising across a full range of legal issues. Our main areas of practice are corporate and commercial, IP and technology, banking and finance, regulatory and real estate. We also have particular expertise in competition & EU law, dispute resolution, employment, pensions and tax.

Our Life Sciences & Healthcare Practice

A key feature of Field Fisher Waterhouse is our focus on industry sectors, and life sciences & healthcare is one of our prime sectors. We have a strong track record advising businesses in the life sciences & healthcare sector on a full range of matters including technology licensing, corporate, dispute resolution, regulatory, data protection, real estate, employment and pensions, patents and trade marks.

By pooling our expertise in the life sciences & healthcare sector across different legal disciplines into an industry group we are able to provide to clients who operate in the sector a joined-up holistic approach to their legal issues on a pan-European basis. It enables us to keep up-to-date with developments in the sector and thereby deliver realistic and practical solutions to our clients' issues.

Several members of our Life Sciences & Healthcare Group have degrees or PhDs in science and medicine and/or are qualified doctors or nurses. This enables us quickly to understand the technology that underpins, and gives value to, our clients' businesses and which is at the heart of a transaction or dispute.

“Field Fisher Waterhouse...has a reputation for providing an excellent all round service to an impressive list of UK and international clients.”
The Legal 500, 2006

Our clients



“the leading firm for healthcare regulatory work”

Legal Business, Corporate Review 2006

Regulatory

Our Regulatory Group is regarded by independent legal directories as one of the most highly rated healthcare practices in the UK. Recently our European expertise in this area was increased by the arrival of a leading EU regulatory team based in our Brussels office and a new partner in Paris. This team, whose members have been recommended by the EU Life Sciences Industry Report for several years running, has an exemplary reputation in product defence and task forces, and deal with issues arising at both the EU and Member State levels.

It advises, lobbies and litigates on EU regulatory matters and has a particular specialism in general chemicals (REACH), pharmaceuticals, biocides, pesticides, biosciences, cosmetics, food, CE marking, biotech, nanotech, the WEEE and RoHS Directives and other environmental regulation. In Paris, we have particular expertise in clinical trials, pharmaceutical distribution, regulatory audit in acquisition operations and disputes regarding liability of laboratories.

We advise regulators of healthcare professionals and healthcare services providers. Our work in this sector has placed our team at the forefront of the development of healthcare law in the regulatory and ethical setting, including advising on human and animal testing. We are familiar with the legislative and regulatory issues relating to the provision of health services within both the publicly-funded and the independent sectors and recognise the political context within which healthcare is provided.

We understand the importance of all stages of the regulatory process from initial research and discussions with the Regulator to making representations and ultimately legal challenge of its decision, if necessary.



Examples of our experience include:

- Recently advising the **Appeal Panel of the Human Fertilisation and Embryology Authority** in relation to a decision not to grant a licence for the transfer of pro-nuclei to de-nucleated eggs. The case involved highly technical arguments as to the embryology technology to be deployed and arguments as to the legal interpretation of the Human Fertilisation and Embryology Act so as to determine whether such research was lawful under the Act.
- Advising a range of commercial clients in the optical sector as well as **Federation of Ophthalmic and Dispensing Opticians (FODO)**, their trade association. We have recently advised FODO on the impact of changes to the regulatory scheme for opticians and in particular the wholesale changes to the way in which contact lenses can be sold and supplied in the UK. Our advice has led to changes in the way high street opticians' practise in this area. We have advised on numerous other areas including the sale of spectacles on the internet.
- Currently advising **Cerner**, the leading US supplier of healthcare information technology solutions on regulatory aspects of its expansion in to the UK market. This has involved performing a regulatory audit and advising on the applicability (or otherwise) of a range of regulatory regimes, including the Medical Devices Regulations and the Waste Electrical and Electronic Equipment Regulations to a range of computer software and hardware as well as dispensing products incorporating the company's technology and branding.

Dispute resolution

We have a group dedicated to IP dispute resolution in the Life Sciences & Healthcare sector. Unlike many firms, IP and technology disputes are not handled by general commercial litigators but IP and technology experts, experienced in all forms of dispute resolution, from mediation to expert determination and, where necessary, litigation. A number of those working on dispute resolution matters have degrees in Life Sciences disciplines or Medicine.

In addition to our dedicated IP and technology dispute resolution team we have a team of general commercial litigators well versed in resolving many different types of commercial dispute, not only in the courts but also by the use of various ADR techniques.

Examples of our experience include:

- Defending **Mediwatch Plc** in US patent infringement proceedings and related United Kingdom infringement issues brought by Diagnostic Ultrasound Corporation in relation to their bladder scanner patent. This action was successfully settled in the client's favour.
- Acting successfully for **PerkinElmer** in its defence of patent infringement proceedings brought by GE Healthcare, Inc. The case related to instrumentation used primarily in pharmaceutical research. The nature of the technology enabled the breadth of the patent team's technical skills to be used to good effect; all have degrees or post-doctorates in an engineering or science discipline (e.g. electronics, genetics, and microbiology). GE claimed infringement of their patent, and PerkinElmer successfully counterclaimed for invalidity for lack of inventive step. GE's Appeal was listed for Feb 2007, but was withdrawn in January 2007.

“ This is a firm where IP/IT is a key practice and as such clients are guaranteed full commitment. ”

The Legal 500, 2005 - IP

- Acting for **Nastech Pharmaceutical Inc** in connection with the revocation of its exclusive pan-European licence of its patented nasal morphine delivery technology for acute pain. Under the terms of the licence, the German exclusive licensee was claiming breach of the licence entitling it not just to a non-exclusive pan-European licence of nasal morphine delivery technology, but to a non-exclusive worldwide licence as well. In commercial terms this meant that the client's ability to generate future revenue from this technology, and to be able to licence it in the future, was potentially severely curtailed. We settled the dispute very favourably.

Corporate

Our corporate group has extensive experience advising on all aspects of establishing, running, developing, acquiring and funding companies. Our core expertise is in M&A, joint ventures, restructurings, venture capital, management buy-out and buy-ins, and fundraisings on the equity markets.

We act for a wide range of clients in the Life Sciences & Healthcare sector. Examples of our lawyers' experience include:

- Advising **AGI Therapeutics plc** on its €85 million flotation on AIM. This Irish based pharmaceuticals company is developing therapies for gastro-intestinal (GI) disorders. The company raised €40 million at flotation which will further its clinical trials in these areas.
- Advising two shareholders in **DIREVO Biotech AG** on its €210 million acquisition by Bayer HealthCare AG. The subsidiary DIREVO Industrial Biotechnology GmbH was sold separately to a group of financial investors. We also advised the lead investors

in the spin-off of Direvos's Industrial business. The sale of DIREVO Biotech AG to Bayer HealthCare AG was the largest ever biotech transaction between a public listed company and a privately held company in Germany.

- We acted for the outgoing majority shareholder in **Lifeways Community Care** on its inward debt and equity investment in Liberty Acquisitions Limited, the acquisition vehicle used by August Equity to acquire Lifeways. This was one of the largest healthcare sector deals in the first half of 2007.
- Advising French company **LVL Medical SA** on its acquisition of Clinovia Healthcare Group, one of the main providers of home healthcare and its subsequent resale to West Private Equity.

We also advise:

- **Aptium Oncology, Inc. and Aptium Cancer Care Limited**
- **Arcadia Biosciences, Inc.**
- **Biovision Energy AG**
- **Cellerix, S.L.**
- **Immunox Therapeutics Limited**
- **Drug Delivery Solutions Limited**

Technology licensing

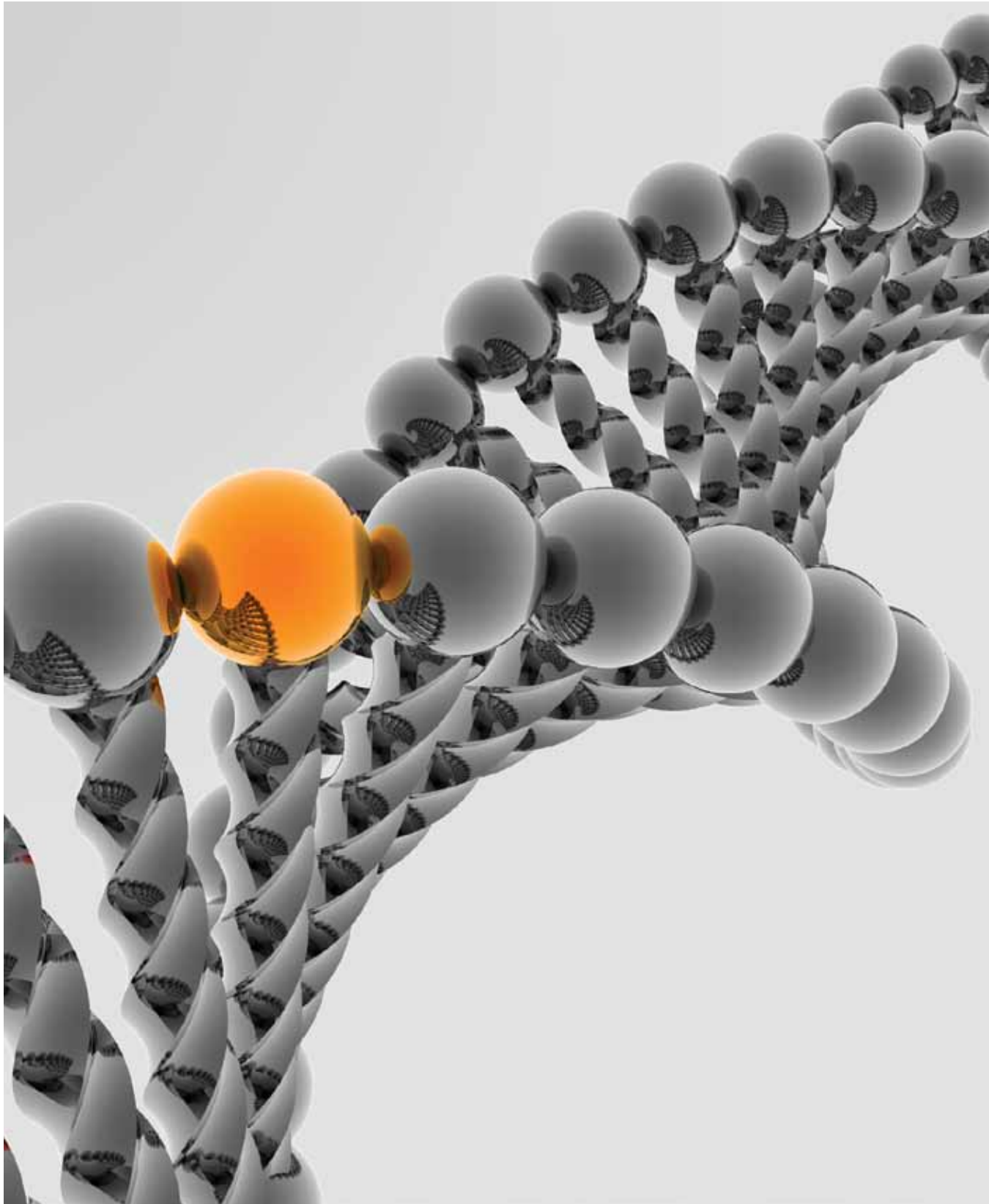
We have one of the largest IP and technology groups among law firms in Europe with almost 100 lawyers working exclusively in these areas. We are recognised by the leading and independently researched legal directories as having leading and recommended practices in all areas of IP law, from the protection of IP of all types to the acquisition, commercialisation and transfer of IP through to IP litigation.





“ This group is warmly commended for its expertise in the healthcare sector; an area in which team members can demonstrate “the skills and experience, wide reach and client care, and knowledge of the business” that have made them popular among clients. ”

Chambers UK, 2006 - Healthcare



“ an excellent reputation amongst regulators and healthcare organisations. ”

The Legal 500, 2005 - Healthcare

We recognise that patents, brands, trade marks, designs, copyrights and other intellectual property rights are the key assets of our clients' businesses. We are organised so as to offer clients comprehensive capabilities across all aspects of IP protection, exploitation and litigation.

The lawyers in our patents practice have degrees in science or engineering and have experience of working in a science or engineering environment.

We have a dedicated team specialising in licensing of all forms of IP rights, and we are well known for patent licensing.

Examples of our experience include:

- We advised a client on the development and commercialisation of micro columnar technology for the analysis of glycosylated haemoglobin and after body fluids. This included confidentiality assignments, licensing, manufacturing, exploitation of know-how and R&D agreements and the creation of a spin-off subsidiary.
- We advised a leading biotech company on its market leading gene threshing technology for the identification and selection of plant structures.
- Acting for **UCL BioMedica Plc** (spun out of University College London) on the exploitation of its European patent for human cytomegalovirus and on its licensing to approximately 45 entities in the UK, and in particular acting on the licensing of this technology to the Health Protection Agency. Preparing and negotiating this company's research agreements with individual researchers.

Additional areas of advice we offer:

Data protection

Our specialist privacy and information law group consists of six partners and three associates. The main legal areas covered by this specialisation are: data protection and privacy law; freedom of information law; the law relating to data retention; and environmental information laws. We are widely regarded as a leading practice in data privacy and we work with some of the most sophisticated organisations in data privacy terms in the UK and the world, such as **Accenture** and **Mercer**.

In a number of instances, we have led discussions regarding data protection compliance and privacy best practice with senior representatives of the Information Commissioner's Office, including Richard Thomas himself, for the benefit of our clients.

Examples of our experience include:

- Advising **IMS Health**, a global source for pharmaceutical market intelligence which provides data to every major pharmaceutical and biotech company in the world, on a programme of business transformation based on centralised hosting and support of global systems, international outsourcing of services and globalised business operations. As part of this process, we are working alongside IMS Health's Chief Privacy Officer to advise on strategic and procedural issues in connection with the adoption of data protection Binding Corporate Rules in all EU Member States.
- Advising the **Royal Pharmaceutical Society** on the regulatory implications of being brought within the UK's freedom of information regime.
- Providing **BP** with data protection advice in relation to the launch of the "PSCM Academy", a new online application and database for the Procurement and Supply Chain Management function within BP

Real estate

In addition to our core commercial real estate practice, within the department we have specialists in planning and environmental law, property litigation, construction and a comprehensive tax capability.

Our approach is twofold: we have specific areas of specialist real estate knowledge and we have industry sector-focused groups, including a Life Sciences & Healthcare Group. Our client base is built upon this approach and includes **BP, AstraZeneca Group plc, ICI Group of Companies and Syngenta**.

The size and skill base of our real estate group is such that we can undertake any property and finance transaction, and our experience of pharmaceutical and industrial companies and the sector within which they operate has enabled us to build up an enviable expertise in terms of dealing with the real estate and tax issues of particular relevance to this industry sector.

Examples of our experience include:

- We deal with all of **AstraZeneca's** UK property requirements. We were recently involved in taking a 40,000sq ft laboratory facility at Cambridge Science Park, and several office buildings at Tytherington Business Park in Macclesfield together comprising approximately 100,000sq ft.
- We have acted for **ICI** and its subsidiaries for nearly 40 years on all of their UK property requirements. Our wide-ranging work encompasses infrastructure projects, developments, the property aspects of business disposals, advising on its office estate, planning and environmental matters and property litigation.
- We have advised the **National Health Service University** on a number of property acquisitions. A major transaction involved a lease of a proposed new headquarters to be situated within the campus of the landlord, the University of Warwick and which will be linked to an education collaboration agreement. Separately, we also act for both the NHS Foundation Trust and the hospitals' charity in connection with their property matters.

Trade marks

Our trade mark & brand protection group advises a multitude of brand owners in a variety of industries, helping them to protect, defend and exploit their brands. It manages over 20,000 brands - one of the largest portfolios in Europe and, according to legal commentaries, has been the best trade mark practice amongst UK law firms for the last six years running. The practice consists of five partners and 11 solicitors together with a support staff of over 30 to handle the day-to-day management of brands in well over 100 countries.

We provide a filing, prosecution and registration service in every country of the world where registration is possible and arrange for protection in those countries where registration is not possible. As an increasing percentage of trade mark applications are challenged by third parties, our expertise is crucial to ensure that our clients' brands are properly protected: both by defending our clients' applications and challenging conflicting applications made by third parties. We are also adept at brand clearance and portfolio brand management for worldwide licensing schemes.

Examples of our experience in the Life Sciences & Healthcare sector include:

- Advising **Masimo Corporation**, a medical apparatus producer on trade mark protection
- Providing **Applera Corporation** with trade mark protection advice and assistance
- Advising **UnitedHealth Group**, large US healthcare company, on trade mark protection

Other clients in the healthcare sector include: **PhotoThera, Inc., Passy-Muir, Inc., Celera Genomics, Acufocus, Inc., Body Wise International, Inc., JEG Diversified Healthcare, Inc., MedScanSonics, Inc., Theravance, Inc., and CardioDynamics International Corporation.**

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